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OVERNIGHT COURIER 4/2/04

Division of Dockets Management
Food and Drug Administration (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, MD 20852

CITIZEN PETITION

Dear Sir or Madam:

The undersigned submits this petition on behalf of a client in quadruplicate, pursuant to 21 CFR 10.30 and in accordance with the regulations at 21 CFR 314.161, requesting the Commissioner of the Food and Drug Administration to provide a determination whether two strengths of a listed drug product have been withdrawn for safety or effectiveness reasons as outlined below.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration determine whether Zoloft (sertraline hydrochloride) Tablets 150 mg and 200 mg (NDA 19-839), manufactured by Pfizer, have been voluntarily withdrawn or withheld from sale for safety or efficacy reasons.

B. Statement of Grounds

The Food and Drug Administration maintains a list of drug products which are eligible for submission as abbreviated new drug applications (ANDAs). The List, referred to as the "Approved Drug Products with Therapeutic Equivalence Evaluations" (Orange Book), contains all FDA-approved drug products. Zoloft Tablets, 150 mg and 200 mg, appear in the discontinued section of the Orange Book. It is not clear whether either of these strengths were ever marketed after original approval on December 30, 1991. The FDA has previously determined "for purposes of 21 CFR 314.161 and 314.162 that never marketing an approved product is equivalent to withdrawing the drug from sale." (65 FR 38561)

Under FDA regulations, drugs are withdrawn from the list if the Agency withdraws or suspends approval of the drug product's application for reasons of safety or effectiveness, or if the FDA determines that the listed drug was withdrawn or withheld from sale for reasons of safety or effectiveness (21 CFR 314.162). The regulations also provide that the Agency must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (21 CFR 314.161(a)(1)).

As stated above, there is no evidence available that the innovator has ever commenced marketing of its Zoloft Tablet, 150 mg or 200 mg products. Therefore, because it appears that there has been no commercial distribution of these drug products, and because the two products appear in the discontinued section of the Orange Book, it is requested that the FDA determine whether Pfizer's decision not to market Zoloft Tablets 150 mg and/or 200 mg was for reasons of safety or effectiveness.

C. Environmental Impact

A claim for categorical exclusion of the requirement for submission of an environmental assessment is made pursuant to 21 CFR 25.31.

D. Economic Impact

Pursuant to 21 CFR 10.30(b) economic impact information is to be submitted only when requested by the Commissioner. This information will promptly be submitted, if so requested.

E. Certification

The undersigned certifies, that to the best of its knowledge and belief, this petition includes all information and views on which the petitioner relies, and that includes representative data and information known to the petitioner that are unfavorable to the petition.

Respectfully submitted,

Robert Pollock

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RWP/pk

cc: Martin Shimer (Office of Generic Drugs)

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